

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A composition comprising an expression vector bound to an aggregated protein-polycationic polymer conjugate which forms a DNA particulate composition, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the expression vector comprises a promoter polynucleotide sequence operatively linked to a polynucleotide sequence encoding an antigen.
2. (Original) The composition of claim 1 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome or gene selected from the group of genomes or genes associated with a disease consisting of infectious disease, cancer, and autoimmune disease.
3. (Original) The composition of claim 2 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome or gene selected from the group of pathogenic genomes consisting of virus, bacterium, fungus and protozoa.
4. (Original) The composition of claim 3 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome selected from the group of viral genomes consisting of HIV, HSV, HCV, influenza and RSV.
5. (Canceled)
6. (Original) The composition of claim 1 wherein the aggregated protein is albumin.
7. (Original) The composition of claim 1 wherein the polycationic polymer is selected from the group consisting of polyamino acids, polyimines or a combination thereof.
8. (Original) The composition of claim 7 wherein the polyimine is polyethyleneimine.
9. (Original) The composition of claim 1 wherein the expression vector contains a heterologous mammalian targeting sequence.
10. (Original) The composition of claim 9 wherein the heterologous mammalian targeting sequence is ubiquitin or a signal sequence for secretion.

11. (Original) The composition of claim 10 wherein the signal sequence for secretion is human growth hormone.
12. (Currently amended) A method of producing a DNA particulate composition comprising the step of incubating an expression vector with an aggregated protein-polycationic polymer conjugate to form the DNA particulate composition, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the expression vector comprises a promoter polynucleotide sequence operatively linked to a polynucleotide sequence encoding an antigen.
13. (Original) The method of claim 12 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome or gene selected from the group of genomes or genes associated with a disease consisting of infectious disease, cancer, and autoimmune disease.
14. (Original) The method of claim 13 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome selected from the group of pathogenic genomes consisting of virus, bacterium, fungus and protozoa.
15. (Original) The method of claim 14 wherein the polynucleotide sequence encoding the antigen is a fragment of a genome selected from the group of viral genomes consisting of HIV, HSV, HCV, influenza and RSV.
16. (Canceled)
17. (Original) The method of claim 12 wherein the expression vector contains a heterologous mammalian targeting sequence.
18. (Original) The method of claim 17 wherein the heterologous mammalian targeting sequence is ubiquitin or a signal sequence for secretion.
19. (Original) The method of claim 18 wherein the signal sequence for secretion is human growth hormone.

20. (Original) The method of claim 12 wherein the polycationic polymer is selected from the group consisting of polyamino acids, polyimines or a combination thereof.
21. (Original) The method of claim 19 wherein the polyimine is polyethyleneimine.
22. (Original) The method of claim 12 wherein the aggregated protein is albumin.
- 23-27 (Canceled)
28. (Currently amended) A method of inducing an immune response in a mammal comprising the step of administering to the mammal an expression vector bound to an aggregated protein-polycationic polymer conjugate which forms a DNA particulate composition, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the expression vector comprises a promoter polynucleotide sequence operatively linked to a polynucleotide sequence encoding an antigen.
29. (Original) The method of claim 28 wherein the immune response is systemic.
30. (Original) The method of claim 28 wherein the immune response is mucosal.
31. (Original) The method of claim 28 wherein the immune response is both systemic and mucosal.
32. (Currently amended) A method of inducing an immune response in a mammal comprising the step of co-administering to the mammal two expression vectors, both bound to an aggregated protein-polycationic polymer conjugate which forms DNA particulate compositions, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the first expression vector comprises a promoter polynucleotide sequence operatively linked to a polynucleotide sequence encoding an antigen and the second vector comprises a cytokine polynucleotide sequence.
33. (Previously Presented) The method of claim 32 wherein the cytokine polynucleotide sequence contains the sequence for GM-CSF.
34. (Previously Presented) The method of claim 32 wherein the cytokine polynucleotide sequence contains the sequence for IL12.

35. (Original) The method of claim 32 wherein the co-administration is to a mucosal surface.
36. (Original) The method of claim 35 wherein the mucosal surface is selected from the group consisting of intranasal surface, oral surface, gastrointestinal surface and genitourinary tract surface.
37. (Original) The method of claim 32 wherein the co-administration is parenterally.
38. (Original) The method of claim 37 wherein the administration is intramuscular and intradermal.
39. (Currently amended) A method of inducing an immune response in a mammal comprising the step of administering to the mammal an expression vector bound to an aggregated protein-polycationic polymer conjugate which forms a DNA particulate composition, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the expression vector comprises a first promoter polynucleotide sequence operatively linked to a first polynucleotide sequence encoding an antigen and a second polynucleotide sequence encoding a cytokine.
40. (Original) The method of claim 39, wherein the first and second polynucleotide sequences are under transcriptional control of the same promoter polynucleotide sequence.
41. (Previously presented) The method of claim 39, wherein the expression vector comprises the first promoter polynucleotide sequence operatively linked to the first polynucleotide sequence encoding an antigen and a second promoter polynucleotide sequence linked to the second polynucleotide sequence encoding a cytokine and the first and second promoter polynucleotide sequences are different.
42. (Currently amended) A method of introducing genes into a cell comprising the steps of: forming a DNA particulate composition comprising an expression vector bound to an aggregated protein-polycationic polymer conjugate, wherein the aggregated protein is not a ligand targeted to a cell surface receptor, and the expression vector comprises a promoter polynucleotide sequence operatively linked to a polynucleotide sequence

encoding an antigen; and incubating the cells with the DNA particulate composition under conditions wherein the cells take in the DNA particulate composition.

43-57 (Canceled)

SUMMARY OF TELEPHONIC INTERVIEW

The Representative for the Applicants, Melissa W. Acosta, conducted a telephonic interview with the Examiner on March 22, 2004 to discuss the pending claims in view of the prior art rejections. The Applicants discussed that the prior art references do not teach the limitation “the aggregated protein is not a ligand targeted to a cell surface receptor”. The Examiner agreed that the addition of this limitation to the claims would obviate the prior art rejections.